



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,957	03/22/2005	Ian Flockhart	B0192.70056US00	8763
23628 7590 10/18/2007 WOLF GREENFIELD & SACKS, P.C. 600 ATLANTIC AVENUE BOSTON, MA 02210-2206			EXAMINER KEYS, ROSALYND ANN	
			ART UNIT 1621	PAPER NUMBER
			MAIL DATE 10/18/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/528,957

Applicant(s)

FLOCKHART ET AL.

Examiner

Rosalynd Keys

Art Unit

1621

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-8, 10-23 and 25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-8, 10-23 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1621

DETAILED ACTION

Status of Claims

1. Claims 1-4, 6-8, 10-23 and 25 are pending.
Claims 1-4, 6-8, 10-23 and 25 are rejected.
Claims 5, 9, and 24 are cancelled.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
3. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

In the present instance, claims 2 and 18 recite the broad recitation purity of 98% or greater , and the claims also recite preferably 99% or

Art Unit: 1621

greater and most preferably 99.5% or greater which is the narrower statement of the range/limitation.

In the present instance, claims 4, 21 and 22 recite the broad recitation less than 1%, and the claim also recites preferably less than 0.8%, more preferably less than 0.6%, more preferably less than 0.4%, more preferably less than 0.2% and most preferably less than 0.1%.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the

Art Unit: 1621

time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-4, 6-8, 10-13, 18-23 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Webster et al. (US 6,403,126 B1) alone or in view of Adams (US 2,304,669) and further in view of Schmidt et al. (US 2003/0017216 A1).

Webster et al. teach a cannabinoid extraction method comprising harvesting Cannabis composed of seed and chaff; separating the chaff from the seed; extracting the chaff with a solvent, thereby producing an extract; passing the extract, if desired, over a chromatographic column arranged to fractionate Δ^9 -THC out of the extract; and collecting the fractions lacking Δ^9 -THC from the column, thereby producing a whole hemp extract without the Δ^9 -THC. The collected fractions may be concentrated (see entire disclosure, in particular column 2, lines 5-23 and column 4, lines 26-48). The extraction solvent may be an organic solvent, which may be selected from a petroleum derived hydrocarbon or supercritical carbon dioxide (see column 2, lines 24-32). The cannabinoid may be selected from cannabidiol (see column 2, lines 56-63). In example I the chaff is pulverized and extracted with a solvent such as hexane. The liquid extract is separated from the solid component by filtration or other means and the extract may then be concentrated or dried and resuspended in a new solvent. In example II the second solvent for extraction is disclosed as a low molecular weight alcohol. In column 6, lines 16 and 17 Webster et al. teach that the cannabinoids may be crystallized.

Webster et al. differ from the instant claims in that Webster et al. do not disclose the purity of their cannabinoids. However, Webster et al. do

Art Unit: 1621

suggest the claimed purity, since Webster et al. desire to obtain a purified cannabinoid which is free of Δ^9 -THC (see column 5, lines 3-25). Further, when claiming a purer form of a known compound, it must be demonstrated that the purified material possess properties and utilities not possessed by the unpurified material. Ex parte Reed, 135 U.S.P.Q. 34, 36 (P.O.B.A. 1961), on reconsideration, Ex parte Reed, 135 U.S.P.Q. 105 (P.O.B.A. 1961). In the instant case the cannibidiol does not appear to have a property or utility not possessed by the cannibidiol of Webster et al.

Webster et al. further differ from the instant claims in the Webster et al. do not disclose the melting point of the crystalline cannibidiol.

Adams discloses that one can obtain a pure crystalline cannibidiol from extracts of hemp (see column 1, lines 1-19). It is taught that the Cannabidiol has a melting point of 66-67° (see column 1, lines 25-27).

One having ordinary skill in the art at the time the invention was made would have found it obvious that the crystalline cannabidiol of Webster has a melting point of 66-67°, since Adams teaches that crystalline cannabidiol has a melting point of 66-67°.

Webster et al. further differ from the claims in that Webster et al. do not specifically disclose utilizing pentane as the solvent. However, Webster et al. do suggest the use of pentane, since Webster et al. disclose the use of a petroleum-derived hydrocarbon as a solvent (see column 4, lines 26-48, in particular lines 37 and 38).

Webster et al. further differ from the instant claims in that Webster et al. do not specifically disclose an initial extraction with liquid carbon dioxide followed by a secondary extraction with another solvent such as ethanol. Webster et al. do however teach that other solvents may be used as modifiers in combination with the supercritical fluid for targeted extraction

Art Unit: 1621

of specific compounds (see example I). Webster et al. also teach that the extract may be suspended in another suitable solvent such as low molecular weight alcohol (see column 2, line 33-48).

Schmidt et al. teach that changing the polarity and hydrophilicity of the extracting solvent systems can modify the ratio of components in the Cannabis oil (see paragraph 0014).

One having ordinary skill in the art at the time the invention was made would have found it obvious to extract the Cannabis of Webster et al. with a combination of a supercritical fluid such as carbon dioxide and another solvent such as ethanol, since Webster et al. teach that combinations of solvent may be utilized for extraction. Further the skilled artisan would be motivated to select the combination of solvents in order to modify the ratio of components in the Cannabis oil, as taught by Schmidt et al.

Webster et al. further differ from the claims in that Webster et al. do not teach a charcoal cleanup step.

Schmidt et al. teach that techniques known to the art such as steam distillation or activated charcoal filtration may optionally be utilized to further enrich the cannabinoid fraction of extracts (see paragraph 0018).

One having ordinary skill in the art at the time the invention was made would have been motivated to utilize a technique such as activated charcoal filtration, as taught by Schmidt et al., on the cannabinoid of Webster et al. in order to obtain a further enriched cannabinoid fraction for medicinal use.

8. Claims 1-4, 6-8, 10-13, 18-23 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whittle et al. (WO 02/064109 A2) in view of Webster et al. (US 6,403,126 B1) and further in view of Schmidt et al. (US 2003/0017216 A1) and Adams et al. (US 2,304,669).

Whittle et al. teach a method of preparing a herbal drug extract

Art Unit: 1621

comprising obtaining medicinal cannabis, chopping the cannabis, heating at a temperature of 100 to 150°C for sufficient time to decarboxylate acid form of cannabinoids to produce neutral cannabinoids, extraction with liquid carbon dioxide, removal of carbon dioxide to recover crude extract, winterization of crude extract in ethanol to precipitate unwanted waxes, removal of unwanted waxy material by cold filtration and removal of ethanol from the filtrate by thin film evaporation under reduced pressure (see example 17 on pages 63 and 64). Whittle et al. teach that one can obtain an extract from a chemovar of cannabis producing more than 90% of its cannabinoid as cannabidiol by supercritical fluid extraction of dried cannabis herb (see page 42, lines 9-13).

Whittle et al. differ from the instant claims in that Whittle et al. do not teach the use of a C5-C12 straight chain or branched alkane or a carbonate ester of a C1-C12 alcohol as the extraction solvent.

Webster et al. teach a process for extraction of a cannabinoid wherein petroleum derived hydrocarbons are interchangeable as extraction solvents with supercritical carbon dioxide.

One having ordinary skill in the art at the time the invention was made would have found it obvious to substitute a petroleum-derived hydrocarbon, as taught by Webster et al., for the liquid carbon dioxide of Whittle et al., since Webster et al. teach that in a process for the extraction of cannabinoids one can use petroleum derived hydrocarbons and supercritical carbon dioxide interchangeably.

Whittle et al. further differ from the claims in that Whittle et al. do not teach treatment of the resulting solution with activated charcoal.

Schmidt et al. teach that techniques known to the art such as steam distillation or activated charcoal filtration may optionally be utilized to

Art Unit: 1621

further enrich a cannabinoid fraction of extracts (see paragraphs, 0007 and 0018).

One having ordinary skill in the art at the time the invention was made would have been motivated to utilize a technique such as activated charcoal filtration, as taught by Schmidt et al., on the cannabinoid of Whittle et al. in order to obtain a further enriched cannabinoid fraction, which is valuable since the cannabinoid has medicinal use.

Whittle et al. further differ from the claims in that Whittle et al. their cannabidiol comprise less than 1% Δ^9 THC.

Webster et al. teach that Cannabis contains a high level of Δ^9 THC which is a psychoactive drug (see column 1, lines 15-43). Webster et al. teach that Δ^9 THC can be removed from the cannabinoid utilizing the steps of their invention.

One having ordinary skill in the art at the time the invention was made would have found it obvious that the Δ^9 THC is removed in the process of Whittle et al., since Whittle et al. conduct some of the same steps utilized in the process of Webster et al.

Whittle et al. do not disclose the melting point or CBD retention time of their cannabidiol. However, since the cannabidiol of Whittle et al. appears to be identical to the claimed cannabidiol it would inherently have the same melting point (66-67°C as taught in column 1, lines 25 and 26 of Adams et al.) and CBD retention time.

Response to Amendment

Content of Specification

9. The objection to the specification for lacking a brief description of the drawing(s) as set forth in 37 CFR 1.74 is withdrawn, due the amendment to

Art Unit: 1621

the specification filed July 23, 2007.

Claim Rejections - 35 USC § 102

10. The rejection of claims 18-22 and 25 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Adams (US 2,304,669) is withdrawn, due the amendment to the claims filed July 23, 2007, which changes these claims from product claims to method claims.

Response to Arguments

Rejection of claims 1-4, 6-8, 10-13, 18-23 and 25 under 35 U.S.C. 103(a) as being unpatentable over Webster et al. (US 6,403,126 B1) alone or in view of Adams (US 2,304,669) and further in view of Schmidt et al. (US 2003/0017216 A1)

11. Applicant's arguments filed July 23, 2007 have been fully considered but they are not persuasive because 1) the claims do not exclude the use of fractionating steps, 2) the use of a chromatographic column is optional in the process of Webster et al. (see column 2, lines 13-15), 3) Webster does teach obtaining purified cannabidiol (see claim 8) free of Δ^9 THC (see column 3, lines 61-65), 4) Webster teaches isolation of the desired cannabinoid (see column 4, lines 6-12) and 5) Webster teaches in Example 1 that the liquid extract is separated from the solid component, for example, by filtration. Further the skilled artisan would reasonably expect that the liquid extract obtained in example 1 contains the desired cannabinoid, for example cannabidiol, since an objective of the Webster is to extract cannabinoids, which can include cannabidiol, from Cannabis (see column 2, lines 40-42 and lines 55-56).

For the above reasons this rejection is maintained.

Rejection of claims 1-4, 6-8, 10-13, 18-23 and 25 under 35 U.S.C. 103(a) as being unpatentable over Whittle et al. (WO 02/064109 A2) in view of Webster

Art Unit: 1621

et al. (US 6,403,126 B1) and further in view of Schmidt et al. (US 2003/0017216 A1) and Adams et al. (US 2,304,669)

12. Applicant's arguments filed July 23, 2007 have been fully considered but they are not persuasive.

The Applicants argue that the skilled person seeking to produce purified CBD would have no motivation to replace the supercritical CO2 extraction of Whittle with the hydrocarbon-based extraction of Webster, even more so since Webster teaches that these are equivalent solvents for the production of general extracts. The Examiner disagrees. The motivation would be to use the extraction solvent of Webster, which is a more readily obtainable alternative to the extraction solvent of Whittle.

The Applicants argue that the skilled person, combining Whittle and Webster, would not consider a further solvent extraction step using a C5-C12 straight chain or branched alkane or carbonate ester of a C1-C12 alcohol (step (b) of claim 1 as amended) to be a suitable improvement upon either method. This argument is not persuasive because Webster teaches that other solvents may be used as modifiers in combination with the supercritical fluid for targeted extraction of specific compounds (see column 5, lines 55-59).

The Applicants argue that even if the skilled person were somehow motivated to substitute solvents, which Applicant contends is not the case, the skilled person would not have a reasonable expectation of success in using a solvent extraction method because Webster teaches that it is necessary to combine a general extraction step with fractionation in order to obtain pure cannabinoids. This argument is not persuasive because Webster teaches that the extract may be fractionated if desired (see column 2, lines 13-14). Thus, the fractionation step is not required, but even if it were the instant claims

Art Unit: 1621

do not preclude the use of a fractionation step. The instant claims may include additional steps besides those claimed.

For the above reasons this rejection is maintained.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosalynd Keys whose telephone number is 571-272-0639. The examiner can normally be reached on M, R & F 5:30-7:30 am & 1-5 pm; T & W 5:30 am-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Rosalynd Keys/
Primary Examiner
Art Unit 1621

October 15, 2007